

## **REMARKS**

### ***Claim Amendments***

Claims 110, 116, and 118 have been amended. Claims 103-109 and 123-124 have been canceled without prejudice or disclaimer to the subject matter therein. Claims 125-128 have been added.

Claims 110 and 118 have been amended to require that the composition consists essentially of at least one bacteriophage that targets said bacterial species, wherein the bacteriophage concentration is  $10^5$ - $10^{11}$  PFU/ml. Support for these amendments may be found, for example, on page 29, lines 21-23; page 31, line 21 to page 32, line 1; page 37, lines 24-26; and page 40, lines 19-20.<sup>1</sup>

Claim 116 has been amended to recite that the bacteriophage targets an antibiotic resistant bacterium or bacterium resistant to disinfectant. Support for this amendment may be found, for example, on page 29, lines 10-12.

Support for new claims 125-128 may be found, for example, on page 29, lines 21-23 and page 40, lines 19-20.

Applicants respectfully request entry of the foregoing above amendment and submit that the above amendment does not constitute new matter.

### ***Statement of Substance of Interview Under 37 C.F.R. § 1.133(b)***

In accordance with 37 C.F.R. § 1.133(b) and M.P.E.P. § 713.04, Applicants herein provide a summary of the interview held on August 2, 2007 with Examiners Stacey B. Chen and Nicole E. Kinsey, Ph.D. ("interview"). Applicants thank Examiners Chen and Kinsey for agreeing to conduct the interview and appreciate the courtesies extended by the Examiners.

During the interview, the parties discussed the rejections set forth in the Office Action and in particular, the Jones et al. reference (EP 0414304 A2). Applicants argued that Jones requires the use of at least one organic surface-active agent (i.e., surfactant). Applicants also pointed out that the bacteriophage concentration actually used and claimed by Jones is  $10^2$ - $10^3$  particles/ml. *See e.g.*, col. 6 and claim 5. Applicants argued that in order for Jones' composition to be effective with a bacteriophage concentration of  $10^2$ - $10^3$  particles/ml, the surfactant must be present and therefore

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<sup>1</sup> The citations referred to herein are taken from the substitute specification filed on May 28, 2004.

materially affects the characteristics of Jones' composition. Applicants argued that Jones does not teach or suggest a bacteriophage composition where the surfactant is not a critical component of the effective composition.

Applicants proposed amending step (b) in claims 110 and 118 to recite a bacteriophage concentration of, for example,  $10^5$ - $10^9$  PFU/ml. Applicants explained that at this concentration the bacteriophage alone is effective in reducing microbial count. Indeed, when the bacteriophage concentration is above  $10^5$  PFU/ml, a surfactant is not required and therefore does not materially affect the characteristics of the composition used in the claims.

Examiner Chen suggested that Applicants further amend step (b) in claims 110 and 118 to recite "providing a composition consisting essentially of..." to make clear that a surfactant is not required.

In the amendment provided herein, Applicants have amended step (b) in claims 110 and 118 to recite "providing a composition consisting essentially of at least one bacteriophage that targets said bacterial species, wherein the bacteriophage concentration is  $10^5$ - $10^{11}$  PFU/ml," covering the ranges disclosed in the specification at pages 29 and 40. New claims 125-128 recite bacteriophage concentrations of  $10^5$ - $10^9$  PFU/ml or  $10^7$ - $10^{11}$  PFU/ml.

### ***Rejections Under 35 U.S.C. §102(b)***

Claims 110-115 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Jones et al. (EP 0 414 304 A2) ("Jones").

Applicants respectfully disagree and traverse this rejection.

Applicants have amended step (b) of claim 110 to recite that the composition consists essentially of at least one bacteriophage that targets said bacterial species, wherein the bacteriophage concentration is  $10^5$ - $10^{11}$  PFU/ml. At this concentration, the bacteriophage alone is effective in reducing microbial count by at least one log. A surfactant is not required and therefore does not materially affect the characteristics of the composition used in the claims.

Indeed, the specification discloses that while bacteriophages may be used with other materials in the claimed invention, these materials are not critical to the essential characteristic of reducing bacteria by at least one log. *See e.g.*, page 31, lines 21 to page 32, line 1. The efficacy of administering such a bacteriophage composition (e.g., as measured by a reduction of bacterial load by at least one log), however, depends on the dose of the bacteriophage. *See e.g.*, page 31, lines 21-26. Accordingly, the specification makes clear that the concentration of the bacteriophage — not an

additional agent such as surfactant — is the essential component capable of reducing microbial load at least one log in the claimed invention.<sup>2</sup>

As discussed during the interview, Jones requires the use of at least one organic surface-active agent (i.e., surfactant). *See e.g.*, col. 2, lines 32-40; col. 3, lines 5-6 and 18-24; col. 6, lines 17-19; and claim 3. Furthermore, the concentration of bacteriophage actually used and claimed by Jones is  $10^2$ - $10^3$  PFU/ml.<sup>3</sup> *See e.g.*, col. 6 and claim 5. In order for Jones' composition to be effective with a bacteriophage concentration of  $10^2$ - $10^3$  particles/ml, the surfactant must be present and therefore materially affects the characteristics of Jones' composition. *See e.g.*, col. 6, lines 17-22 (showing an example of contacting a ceramic tile with an aqueous composition containing  $10^3$  particles/ml of a bacteriophage against *E. coli*, 1% Tween 80 (a surfactant) and 0.01% sodium chloride). Jones does not teach or suggest a bacteriophage composition where the surfactant is not a critical component of the effective composition. Furthermore, attempts to optimize the compositions of Jones, which contain both bacteriophage and surfactant, would not permit one to discover any effect of bacteriophage in the absence of surfactant. Accordingly, because Jones does not teach a step of providing a composition consisting essentially of at least one bacteriophage, wherein the bacteriophage concentration is  $10^5$ - $10^{11}$  PFU/ml, Applicants submit that Jones does not anticipate the claimed invention.<sup>4</sup>

In view of the foregoing, Applicants respectfully request withdrawal of this rejection.

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<sup>2</sup> Applicants note teachings in the art that surfactants are capable of reducing microbial activity on their own. *See e.g.*, Ishikawa et al. Journal of Applied Microbiology (2002), 93: 320-309, attached herewith as **Exhibit A**.

<sup>3</sup> Applicants note that while Jones mentions that the composition may comprise at least  $10^2$ , preferably more than  $10^3$  particles/ml, Jones offers no mention of a composition consisting essentially of at least one bacteriophage, where the bacteriophage concentration is in the range of  $10^5$ - $10^{11}$  PFU/ml.

<sup>4</sup> Applicants also submit that Jones does not teach applying such a composition to a hard surface as required by step (c).

***Rejections Under 35 U.S.C. § 103(a)***

Claims 103-109 and 116-124 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Jones, in view of Holzman (Genetic Engineering News, hereinafter “Holzman”), and Day *et al.* (GB 2 253 859, hereinafter “Day”).

Applicants respectfully disagree and traverse this rejection.

Applicants have canceled claims 103-109 and 123-124. As discussed above, Applicants have amended claims 110 (from which claims 116-117 depend) and claim 118 (from which claims 119-122 depend). Applicants submit that the cited references alone, or in combination, do not teach or suggest each and every claim limitation for the reasons discussed below.

**Claims 116 and 117**

The Office Action states that Jones discloses a method for sanitizing hard surfaces (e.g., toilet bowls) by applying a composition comprising at least one bacteriophage to the hard surface. The Office Action states that it is common knowledge that hard surfaces (e.g., toilet bowls) are located in hospitals where immunocompromised patients receive treatment. The Office Action acknowledges, however, that Jones does not teach using bacteriophages that target resistant bacteria. *See* O.A. at pages 2-4.

As discussed above, Jones does not teach or suggest a step of providing a composition consisting essentially of at least one bacteriophage, wherein the bacteriophage concentration is  $10^5$ - $10^{11}$  PFU/ml.

The Office Action states that Day discloses the use of bacteriophage compositions to treat or prevent infestation of microbes, where the compositions may be applied to hard surfaces such as floors and drains. *See* O.A. at page 4. Day, however, does not provide any reason to modify Jones to provide the composition recited in step (b) of claim 110 (i.e., containing bacteriophage at a concentration of  $10^5$ - $10^{11}$  PFU/ml).<sup>5</sup>

The Office Action cites Holzman for the proposition that phages are used to treat multi-drug resistant bacterial infections. *See* O.A. at page 5. Indeed, Holzman relates to therapy of individuals and does not teach or suggest applying bacteriophage to a hard surface, let alone a

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<sup>5</sup> Applicants acknowledge that Day claims a method of using bacteriophages, wherein the bacteriophage concentration is about  $10^2$ - $10^{11}$  PFU. *See* Claim 6. Day's range with respect to bacteriophages used in areas where foodstuffs are prepared, however, is coincident with the range disclosed with Jones ( $>10^2$  particles/ml), and would not motivate one of ordinary skill in the art to modify Jones to provide the composition recited in step (b) of claim 110.

method of sanitizing a hard surface contaminated by a bacterial species and located in an area accessed by immunocompromised patients, wherein bacteriophage targets an antibiotic resistant bacterium or bacterium resistant to disinfectant. Holzman also does not disclose any bacteriophage concentrations, and thus does not provide any reason to modify Jones and/or Day to provide the composition recited in step (b) of claim 110.

Accordingly, Applicants submit that the cited references alone, or in combination, do not teach or suggest each and every claim limitation in claims 116 and 117.

#### **Claims 118-122**

The Office Action states that Jones does not teach a method of using bacteriophages to sanitize equipment. *See* O.A. at page 4.

The Office Action states that Day discloses the use of bacteriophage compositions to treat or prevent infestation of microbes, where the compositions may be applied to hard surfaces such as floors and drains. *See* O.A. at page 4. Day, however, does not provide any reason to modify Jones to apply bacteriophages to equipment, let alone a method of sanitizing equipment.

The Office Action cites Holzman for the proposition that phages are used to treat multi-drug resistant bacterial infections. *See* O.A. at page 5. Indeed, Holzman relates to therapy of individuals and does not teach or suggest applying bacteriophage to equipment, let alone a method of sanitizing equipment.

Accordingly, Applicants submit that the cited references alone, or in combination, do not teach or suggest each and every claim limitation in claims 118-122.<sup>6</sup>

In view of the foregoing, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 103.

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<sup>6</sup> Applicants also submit that the cited references alone, or in combination, do not teach or suggest each and every claim limitation in claims 118-122 for the reasons discussed in section relating to claims 116 and 117.

### CONCLUSION

In view of the foregoing, Applicants respectfully request an indication of allowance of all claims.

If the Examiner has any questions relating to this response, or the application in general, she is respectfully requested to contact the undersigned so that prosecution of this application may be expedited.

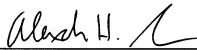
Concurrently with this paper, Applicants are filing a Request for Continued Examination that authorizes the Commissioner to charge **Deposit Account No. 50-0206** in the amount of \$395.00 (small entity). Applicants believe that no additional fees are required for entry of this paper, but should any fees be required for entry and consideration of this amendment and response, the Commissioner is authorized to charge such fees to **Deposit Account No. 50-0206**.

Respectfully submitted,

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